



International Dairy Foods Association
Milk Industry Foundation
National Cheese Institute
International Ice Cream Association

August 12, 2005

Arthur Neal
Director, Program Administration
National Organic Program
USDA-AMS-TMO-NOP
1400 Independence Ave., SW. Room 4008
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Washington, DC 20250

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RE: National Organic Program, Sunset Review
Docket number TM-04-07

Dear Mr. Neal and National Organic Standards Board:

The International Dairy Foods Association (IDFA) appreciates the opportunity to comment on the draft report, "Approaches to Establish Thresholds for Major Food Allergens and for Gluten in Food." These comments are submitted on behalf of IDFA and its constituent organizations, the Milk Industry Foundation, the International Ice Cream Association, and the National Cheese Institute. The approximately 500 member companies of these associations operate more than 650 processing and manufacturing plants, which account for 85% of the dairy products consumed in the United States.

Please find our comments in the following attachment.

Respectfully submitted by,

Cary P. Frye
Vice President, Regulatory Affairs

cc: National Organic Standards Board

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IDFA supports the continued allowance of the following substance(s):

Name of Substance	Location on National List	Reason for Continued Allowance/ Common use	Supporting Documents in additional reports
Alginic acid	205.605(a)	Stabilizer; emulsifier, gelling agent, thickener; No other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process.	<ul style="list-style-type: none"> • 21 CFR 184.1011 • NOSB 4/95 • International Organic Regulations Codex, Japan
Citric Acid	205.605(a)	Acidity regulator; Alternatives have not been available on a commercial scale.	<ul style="list-style-type: none"> • 21 CFR 184.1033 • International Organic Regulations Codex, EU, Japan
Lactic Acid	205.605(a)	Acidity regulator; Alternatives have not been available on a commercial scale.	<ul style="list-style-type: none"> • 21 CFR 184.1061 • International Organic Regulations Codex, EU, Japan
Agar	205.605(a)	Thickening agent; No other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process.	<ul style="list-style-type: none"> • 21 CFR 184.1115 • NOSB 4/95
Ascorbic acid	205.605(b)	Preservative meats, produce; acidity regulator; nutrient (Vitamin C); antioxidant; Alternatives have not been available on a commercial scale.	<ul style="list-style-type: none"> • 21 CFR 182.8013, 145.110, 145.146.185, 146.187 • NOSB 04/95 • International Organic Regulations Codex, Japan
Calcium carbonate	205.605(a)	Calcium fortification; No other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process. Alternatives have not been available on a commercial scale.	<ul style="list-style-type: none"> • 21 CFR 184.1191 • NOSB 11/95
Calcium chloride	205.605(a)	Calcium fortification; There are alternative methods of providing calcium to crops and for postharvest handling. In some cases, calcium chloride is the most effective way to prevent disease. One example is its use on apples as a foliar spray and as a postharvest dip to protect against bitter pit. This has already been approved by the NOSB. Although there are alternatives for providing calcium to crops, in some situations, calcium chloride is the only effective material that prevents certain diseases.	<ul style="list-style-type: none"> • 21 CFR 184.1193 • NOSB 4/95 • International Organic Regulations Codex, Japan, EU, IFOAM

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Calcium citrate	205.605(b)	Calcium fortification; No other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process. Alternatives have not been available on a commercial scale.	<ul style="list-style-type: none"> • 21 CFR 184.1195 • NOSB 11/95 • International Organic Regulations
Calcium hydroxide	205.605(b)	Calcium fortification; Processing aid; Calcium hydroxide is listed as an approved synthetic nonagricultural substance allowed as an ingredient in organic processed food. No other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process.	<ul style="list-style-type: none"> • 21 CFR 184.1205 • NOSB 04/95 • International Organic Regulations
Calcium hypochlorite	205.601(a)	Sanitizer; Antimicrobial; No other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process.	<ul style="list-style-type: none"> • 21 CFR 178.1010 • NOSB 11/95
Calcium phosphates (mono, di, tribasic)	205.605(b)	Leavening agent; calcium supplement; No other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process.	<ul style="list-style-type: none"> • 21 CFR 182.1217 • NOSB 11/95 • International Organic Regulations
Calcium sulfate	205.605(a)	Natural bleaching agent for milk used in the cheese making process in place of adding colors directly to the cheese. Coagulant for soymilk, helps fruits and vegetables retain firmness, dough conditioner; Substitute not available.	<ul style="list-style-type: none"> • 21 CFR 184.1230 • NOSB 3/01 Synthetic: NOSB 9/95
Carbon dioxide	205.605(b)	Activating agent; carbonation; No other way to produce a similar product without its use; No commercially available alternatives.	<ul style="list-style-type: none"> • 21 CFR 165.110, 184.1240 • NOSB 11/95 • International Organic Regulations Codex, EU, Japan
Carrageenan	205.605(a)	Thickening agent; No known suitable substitutes that would achieve same result.	<ul style="list-style-type: none"> • 21 CFR 172.620, 182.7255 • NOSB 4/95 • International Organic Regulations
Cellulose	205.605(b)	Anticaking agent; filtering aid; There are very small amounts of bacterial-derived cellulose available but have not been used in food production; No other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process.	<ul style="list-style-type: none"> • 21 CFR Part 172 Food additives permitted for addition to food for human consumption 172.870, 172.872, 172.874

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Chlorine dioxide	205.601(a)	Sanitizer; Antimicrobial; No other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process.	<ul style="list-style-type: none"> • 21 CFR 173.300, 178.1010 • NOSB 11/95
Chlorine Materials	205.605(b)	Sanitizer; No other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process.	<ul style="list-style-type: none"> • 40 CFR 141.72 • NOSB 11/95
Colors, non-synthetic	205.605(a)	Coloring agent; Nutrient value from fruit/vegetable extract; Essential to produce food and beverage products that would be acceptable to consumers, does not have adverse nutritional impact.	<ul style="list-style-type: none"> • 21 CFR 101.22 Spices and spice • Fruit/Vegetable extracts
Cornstarch (native)	205.606	Thickening agent; § 205.606 states, "Any non organically produced agricultural product may be used in accordance with the restrictions specified in this section and when the product is not commercially available in organic form." The organic corn starch now available is not enough to cover all commercial needs and is not economically feasible.	<ul style="list-style-type: none"> • Corn starches have been affirmed for use on food contact surfaces in 21 CFR 184.127. Dextrins have also been affirmed for use by the Food and Drug Administration. Regulations may be found in 21 CFR 184.127. • NOSB 11/95
Dairy cultures	205.605(a)	Fortify products with live cultures; Flavor dairy products; Manufacture of cheese; No other way to produce a similar product without its use.	<ul style="list-style-type: none"> • NOSB 10/95
Diatomaceous earth	205.605(a)	Clarifying agent; Sanitizer; No other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process.	<ul style="list-style-type: none"> • NOSB 4/95 • International Organic Regulations Codex, EU, Japan
Enzymes	205.605(a)	Broad use; No other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process.	<ul style="list-style-type: none"> • 21 CFR Part 184, 21 CFR Part 172 • NOSB 11/00 animal derived • NOSB 4/95 bacterial derived • NOSB 10/99 fungal derived • NOSB 10/99 plant derived • International Organic Regulations
Ferrous sulfate (Iron)	205.605(b)	Fortification; No other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process.	<ul style="list-style-type: none"> • 21 CFR 184.1315 • NOSB 4/95

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Flavors, non-synthetic	205.605(a)	Flavor enhancer; Nonsynthetic sources only and must not be produced using synthetic solvents and carrier systems or any artificial preservative; Alternatives have not been available on a commercial scale; Essential to produce food and beverage products that would be acceptable to consumers, does not have adverse nutritional impact.	<ul style="list-style-type: none"> 21 CFR 101.22 Definition of Natural flavor or natural flavoring; oleoresin, essence or extractive, distillate, or any product of roasting or enzymolysis, which contains the flavor derived from a spice, fruit or fruit juice, vegetable juice, edible yeast, herb or similar plant material, meat, seafood products, or fermentation products; significant function in food is flavoring; nutritional. Natural flavors include extracts obtained from plants listed in 182.20, 182.40, and 182.50 and products and the substances listed in § 172.161. 21 CFR 182.10, 182.20, 182.40, 182.50 NOSB 10/95
Glucono delta-lactone	205.605(a)	Direct acidification agent for manufacture of acidified milk and cheese. Essential to produce the thickened texture and flavor for acidified dairy products that is acceptable for consumers, does not have adverse nutritional impact.	<ul style="list-style-type: none"> 21 CFR 184.1818 NOSB 2004
Glycerides (mono & di)	205.605(b)	Emulsifier; No other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process.	<ul style="list-style-type: none"> 21 CFR 184.1505 NOSB 4/95
Glycerin	205.605(b)	Stabilizer; emulsifier; Widely used in the manufacture of organic/natural flavors.	<ul style="list-style-type: none"> 21 CFR 182.1320, 169.175 NOSB 11/95
Gums (water extracted-arabic, guar, locust (carob) bean)	205.606	Stabilizer, emulsifier, gelling agent, thickener; Alternatives have not been available on a commercial scale that will deliver with same results for specific products.	<ul style="list-style-type: none"> 21 CFR 184.1330, 184.1333, 184.1351, 184.1349 NOSB 11/95 International Organic Regulations Codex, EU, Japan
Hydrogen peroxide	205.605(b)	Aseptic packaging; No other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process.	<ul style="list-style-type: none"> 21 CFR 178.1005 NOSB 11/95 International Organic Regulations

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Lecithin-bleached	205.605(b)	Emulsifier; More beneficial ingredient than most of its alternatives in emulsifying products. § 205.606 states, "Any non organically produced agricultural product may be used in accordance with the restrictions specified in this section and when the product is not commercially available in organic form." The organic liquid lecithin now available is not enough to cover all commercial needs, is not economically feasible, and the quality of the organic fluid lecithin is not acceptable.	<ul style="list-style-type: none"> • Lecithin is considered to be GRAS, 21 CFR 184, Sec 184.1400 • NOSB 4/95 • International Organic Regulations Codex, EU, Japan
Lecithin (unbleached)	205.606	Emulsifier; More beneficial ingredient than most of its alternatives in emulsifying products. § 205.606 states, "Any non organically produced agricultural product may be used in accordance with the restrictions specified in this section and when the product is not commercially available in organic form." The organic liquid lecithin now available is not enough to cover all commercial needs, is not economically feasible, and the quality of the organic fluid lecithin is not acceptable.	<ul style="list-style-type: none"> • Lecithin is considered to be GRAS, 21 CFR 184, Sec 184.1400 • NOSB 4/95 • International Organic Regulations Codex, EU, Japan
Magnesium chloride	205.605(b)	Protein coagulant;	<ul style="list-style-type: none"> • 21 CFR 184.1426 • NOSB 11/95 and 10/99 • International Organic Regulations
Nitrogen(oil free)	205.605(a)	No other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process.	<ul style="list-style-type: none"> • 21 CFR 184.1540 • NOSB 4/95 • International Organic Regulations
Nutrient Minerals	205.605(b)	Fortification; No other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the product. Non-synthetic versions are not widely available commercially. These are required to be used in many products to comply with FDA regulations.	<ul style="list-style-type: none"> • 21 CFR 104.20 • NOSB 10/95 • International Organic Regulations

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Nutrient Vitamins	205.605(b)	Fortification; No other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the product. Non-synthetic versions are not widely available commercially. These are required to be used in many products to comply with FDA regulations.	<ul style="list-style-type: none"> • 21 CFR 104.20 • NOSB 10/95 • International Organic Regulations
Ozone	205.605(b)	Sanitizer; No other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process.	<ul style="list-style-type: none"> • 21 CFR 173.368, 184.1563 • NOSB 11/95
Pectin(low-methoxy)	205.605(b)	Thickening agent; Specific to certain products to achieve needed results. No other way to produce desired product without its use.	<ul style="list-style-type: none"> • 21 CFR 184.1588 • 21 CFR Parts 145, 126, 131, 136, 140, 160, 161 • NOSB 4/95 • International Organic Regulations Codex, EU, Japan
Pectin (high-methoxy)	205.606	Thickening agent; Specific to certain products to achieve needed results. No other way to produce desired product without its use.	<ul style="list-style-type: none"> • 21 CFR 184.1588 • 21 CFR Parts 145, 126, 131, 136, 140, 160, 161 • NOSB 4/95 • International Organic Regulations Codex, EU, Japan
Phosphoric Acid	205.605(b)	Sanitizer; Compatible with sustainable agriculture and there are no clear alternatives with less compromise of organic integrity.	<ul style="list-style-type: none"> • 21 CFR 182.1073 • NOSB 10/99 • USDA dairy division list of cleaning
Potassium citrate	205.605(b)	Emulsifier; Alternatives will not deliver product with same quality.	<ul style="list-style-type: none"> • 21 CFR 184.1625 • NOSB 4/95 • International Organic Regulations
Potassium hydroxide	205.605(b)	Fortification; No other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process.	<ul style="list-style-type: none"> • 21 CFR 184.1631 • NOSB 11/95 • International Organic Regulations
Potassium phosphate	205.605(b)	Fortification; No other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process.	<ul style="list-style-type: none"> • 21 CFR 184.1643 • NOSB 4/95

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Potassium acid tartrate	205.605(b)	Leavening agent, pH buffer; No other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process.	<ul style="list-style-type: none"> • 21 CFR 184.1077 • NOSB 11/95 • International Organic Regulations
Silicon dioxide	205.605(b)	Anticaking agent; No other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process.	<ul style="list-style-type: none"> • 21 CFR 172.480 • NOSB 9/96 • International Organic Regulations
Sodium bicarbonate	205.605(a)	Leavening agent, pH buffer; No other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process.	<ul style="list-style-type: none"> • 21 CFR 184.1736 • NOSB 4/95 • International Organic Regulations
Sodium citrate	205.605(b)	Emulsifier; Alternatives will not deliver product with same quality.	<ul style="list-style-type: none"> • 21 CFR 184.1751 • NOSB 4/95 • International Organic Regulations
Sodium hydroxide	205.605(b)	Sanitizer; pH adjuster; No other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process.	<ul style="list-style-type: none"> • 21 CFR 178.1010, 184.1763 • NOSB 4/95 • International Organic Regulations Japan
Sodium hypochlorite	205.601(a)	Sanitizer; Antimicrobial; No other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process.	<ul style="list-style-type: none"> • 21 CFR 178.1010 • NOSB 11/95
Sodium phosphates	205.605(b)	Emulsifier; pH buffer, stabilizer; Essential to produce food and beverage products that would be acceptable to consumers, does not have adverse nutritional impact; There are no non synthetic sources available.	<ul style="list-style-type: none"> • Considered to be GRAS as multiple uses under CFR 21, Part 182, Sec 182.2 • Organic Regulations: Australia, Canada, Japan • NOSB 11/95
Tartaric acid	205.605(a), 205.605(b)	pH adjuster	<ul style="list-style-type: none"> • 21 CFR 184.1099 • NOSB 11/95
Tetra sodium pyrophosphate	Approved in 2004	Emulsifier; pH buffer, stabilizer.	<ul style="list-style-type: none"> • 21 CFR 182.6789 • EPA inert ingredient list • NOSB 2004 (need to add to list)

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Tocopherols	205.605(b)	Antioxidant; Fortification; Alternatives not enough to cover all commercial needs and not economically feasible.	<ul style="list-style-type: none"> • 21 CFR 182.3890 • NOSB 11/95
Xanthan gum	205.605(b)	Thickening agent; Alternatives have not been available on a commercial scale that will deliver product with same quality.	<ul style="list-style-type: none"> • 21 CFR 172.695 • NOSB 4/95 • International Organic Regulations Codex, EU
Yeast	205.605(a)	Vitamin B source, production of bread and bread products. No other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process.	<ul style="list-style-type: none"> • 21 CFR 184.1983, 172.325, 172.326 • NOSB 11/95 • International Organic Regulations